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Effect of elinzanetant on sleep disturbance and aspects of quality of life in women with breast cancer experiencing vasomotor symptoms: OASIS-4 subgroup analysis by type of endocrine therapy

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Key takeaways

Elinzanetant demonstrated rapid and sustained improvements in sleep disturbance compared with placebo irrespective of type of background endocrine therapy

Improvements were also seen in vasomotor, psychosocial, physical, and sexual aspects of menopause-related quality of life

Taken with previous data, findings support the efficacy of elinzanetant in reducing VMS frequency and severity, as well as sleep disturbance, and improving menopause-related quality of life independently of the type of endocrine therapy

VMS, vasomotor symptoms.

Introduction

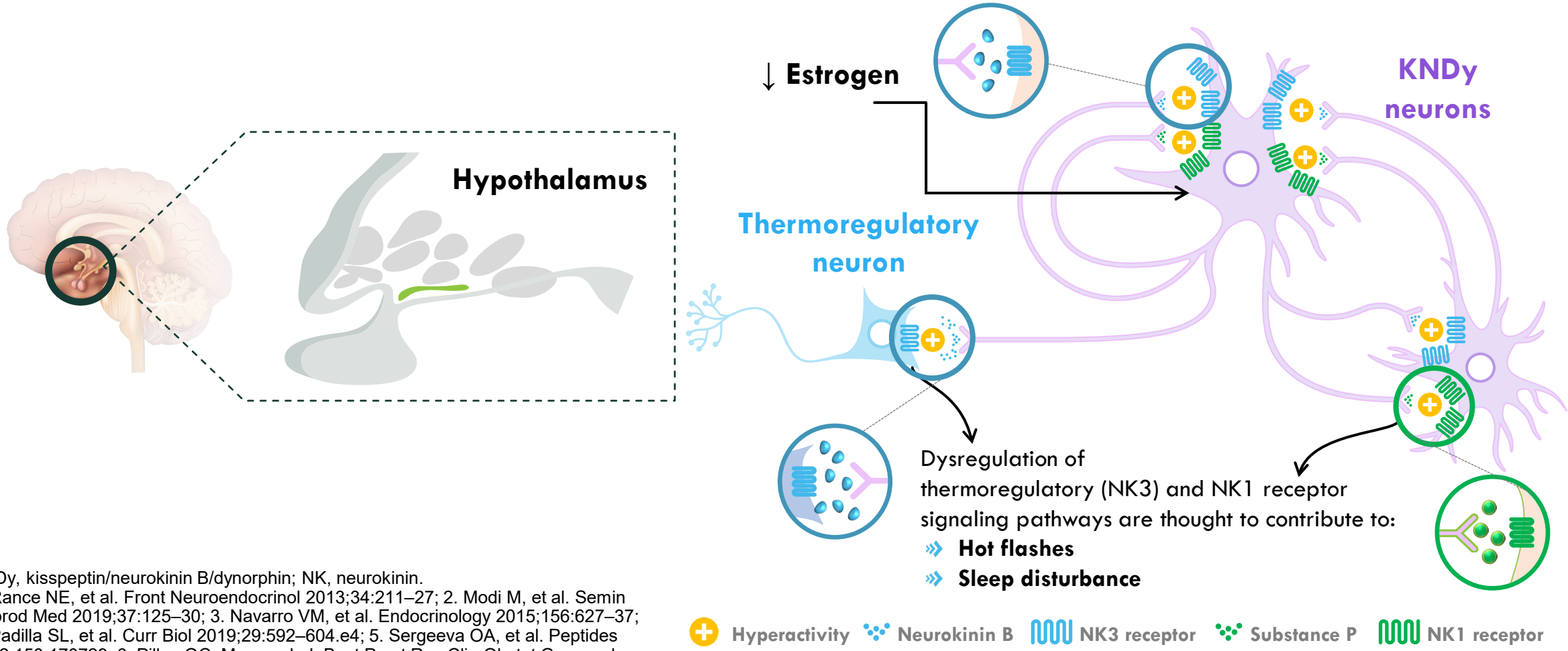
Elinzanetant is the first and only dual neurokinin (NK)-targeted therapy (NK1 and NK3 receptor antagonist) approved in several countries for the non-hormonal treatment of VMS associated with menopause and in the EU for VMS caused by endocrine therapy for breast cancer

In the Phase III OASIS-4 trial, elinzanetant demonstrated rapid, significant, and sustained improvements in VMS, sleep disturbance, and menopause-related quality of life in women taking endocrine therapy for breast cancer

This subgroup analysis evaluated the effect of elinzanetant on sleep disturbance and quality of life by type of endocrine therapy in OASIS-4

EU, European Union; NK, neurokinin; VMS, vasomotor symptoms.

Background: what may be the link between menopause, thermoregulation, and sleep?[1–8]

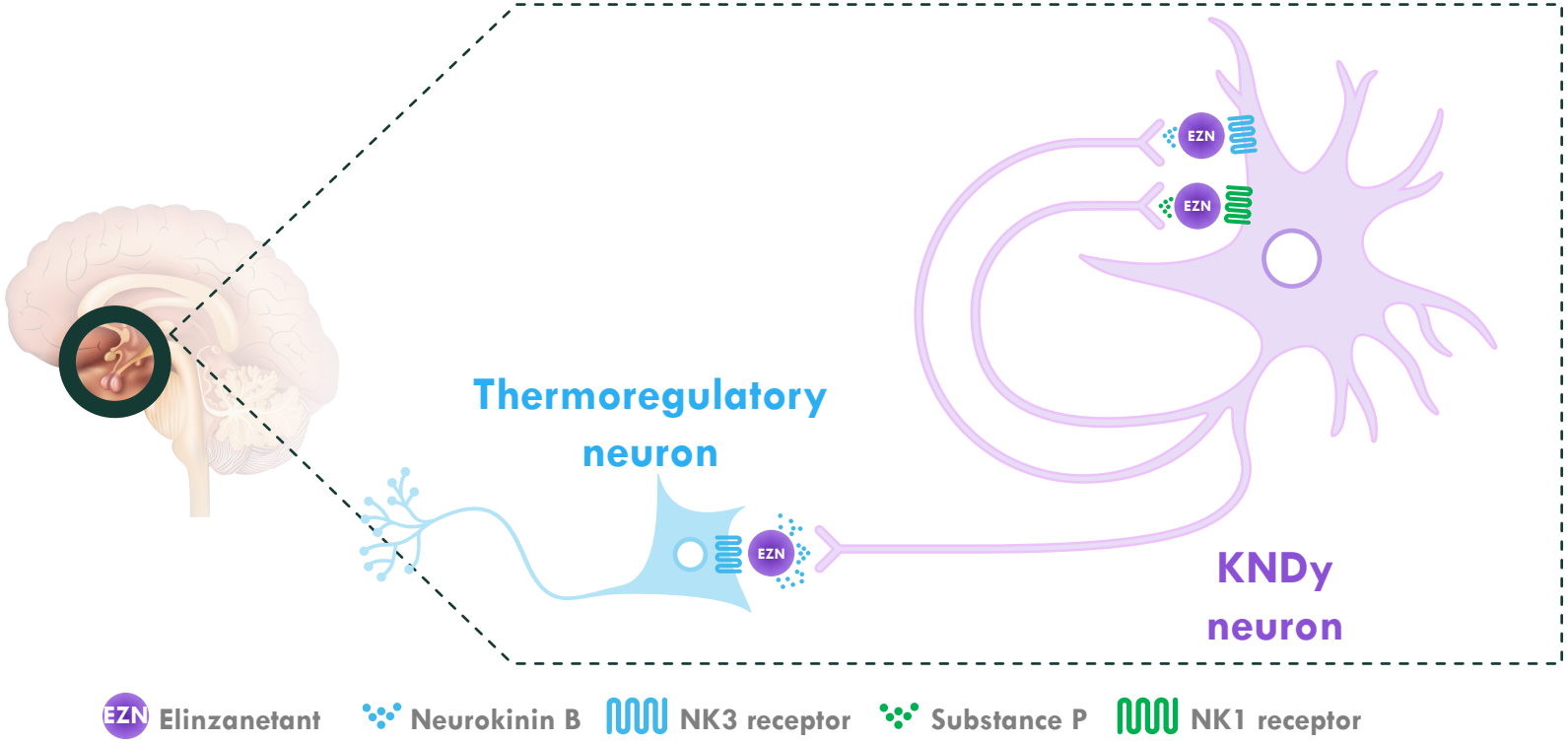


KNDy, kisspeptin/neurokinin B/dynorphin; NK, neurokinin.

1. Rance NE, et al. Front Neuroendocrinol 2013;34:211–27; 2. Modi M, et al. Semin Reprod Med 2019;37:125–30; 3. Navarro VM, et al. Endocrinology 2015;156:627–37; 4. Padilla SL, et al. Curr Biol 2019;29:592–604.e4; 5. Sergeeva OA, et al. Peptides 2022;150:170729; 6. Pillay OC, Manyonda I. Best Pract Res Clin Obstet Gynaecol 2022;81:111–8; 7. Shifren JL, et al. Menopause 2014;21:1038–62; 8. Zhang Z, et al. Elife 2021;10:e63333.

Background: elinzanetant's mode of action

Recent evidence indicates that by targeting **NK1** and **NK3** receptors found centrally in the **hypothalamus**, as well as **NK1** receptors in the **skin**, elinzanetant may contribute to restoring temperature regulation and sleep[1–5]

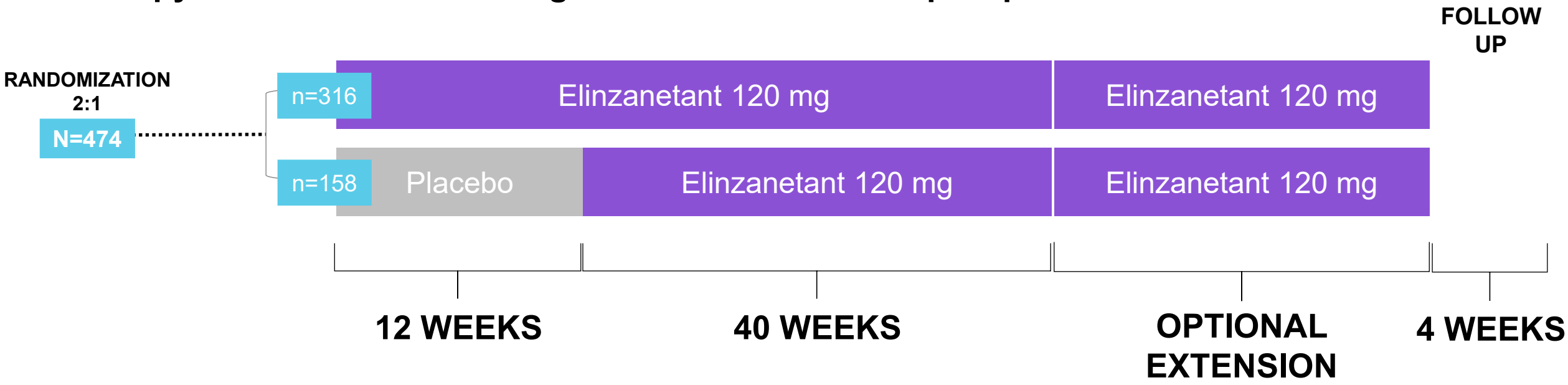


KNDy, kisspeptin/neurokinin B/dynorphin; NK, neurokinin.

1. Pinkerton JV, et al. JAMA 2024;332:1343–54; 2. Simon JA, et al. Menopause 2023;30:239–46; 3. Cardoso F, et al. N Engl J Med 2025;393:753–63; 4. Panay N, et al. JAMA Intern Med 2025;185(11):1319–27; 5. Wong BJ, Minson CT. J Physiol 2006;577:1043–51.

Study design

OASIS-4 (NCT05587296) was a **multicenter, randomized, double-blind, placebo-controlled** Phase III trial evaluating elinzanetant 120 mg for the treatment of **VMS associated with endocrine therapy in women with or at high risk of hormone receptor-positive breast cancer.**



Women who completed 52 weeks of treatment were able to participate in an ongoing extension for up to 3.5 years

VMS, vasomotor symptoms.

Study design

Key inclusion criteria	» Women aged **18–70** years » Taking **endocrine therapy** (tamoxifen or aromatase inhibitors with or without GnRH analogs) for HR+ breast cancer » Experiencing **≥35 moderate-to-severe hot flashes per week**
Endpoints reported in this presentation	Mean change from baseline to week 12 in: » PROMIS SD SF 8b total T-score (degree of sleep disturbance) » MENQOL total score (menopause-related quality of life assessed through level of bother across vasomotor, psychosocial, physical, and sexual domains)
Analysis	Endpoints were analyzed descriptively by type of **endocrine therapy** at baseline: » Tamoxifen » Aromatase inhibitors » With GnRH » Without GnRH

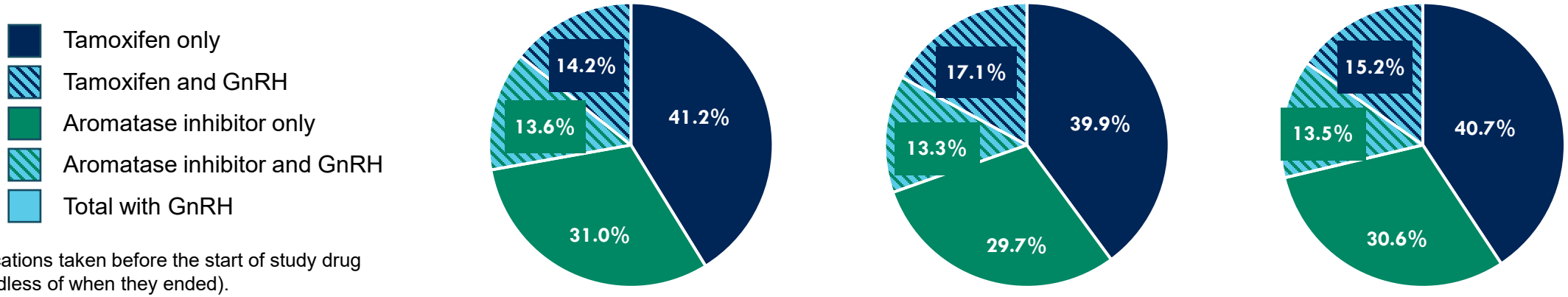
Reductions in VMS frequency and severity by type of endocrine therapy have been previously described[1]

GnRH, gonadotrophin-releasing hormone; HR+, hormone receptor-positive; PROMIS SD SF 8b, Patient-Reported Outcomes Measurement Information System Sleep Disturbance Short Form 8b; MENQOL, Menopause-specific Quality Of Life questionnaire; VMS, vasomotor symptoms.

1. Cardoso F, et al. Presented at EBCC 2026.

Prior adjuvant endocrine therapy* (FAS)

Drug / drug class	Elinzanetant 120 mg (n=316)	Placebo–Elinzanetant 120 mg (n=158)	Total (N=474)
Number (%) of subjects	**316 (100.0%)**	**158 (100.0%)**	**474 (100.0%)**
Duration of adjuvant endocrine therapy (years), mean (SD)	2.0 (1.5)	1.8 (1.5)	1.9 (1.5)
Tamoxifen	**175 (55.4%)**	**90 (57.0%)**	**265 (55.9%)**
Tamoxifen with GnRH	45 (14.2%)	27 (17.1%)	72 (15.2%)
Aromatase inhibitors	**141 (44.6%)**	**68 (43.0%)**	**209 (44.1%)**
Aromatase inhibitors with GnRH	43 (13.6%)	21 (13.3%)	64 (13.5%)
Total with GnRH	**88 (27.8%)**	**48 (30.4%)**	**136 (28.7%)**



Elinzanetant 120 mg (n=316)

Placebo–Elinzanetant 120 mg (n=158)

Total (N=474)

*Medications taken before the start of study drug (regardless of when they ended).
FAS, full analysis set; GnRH, gonadotropin-releasing hormone; SD, standard deviation.

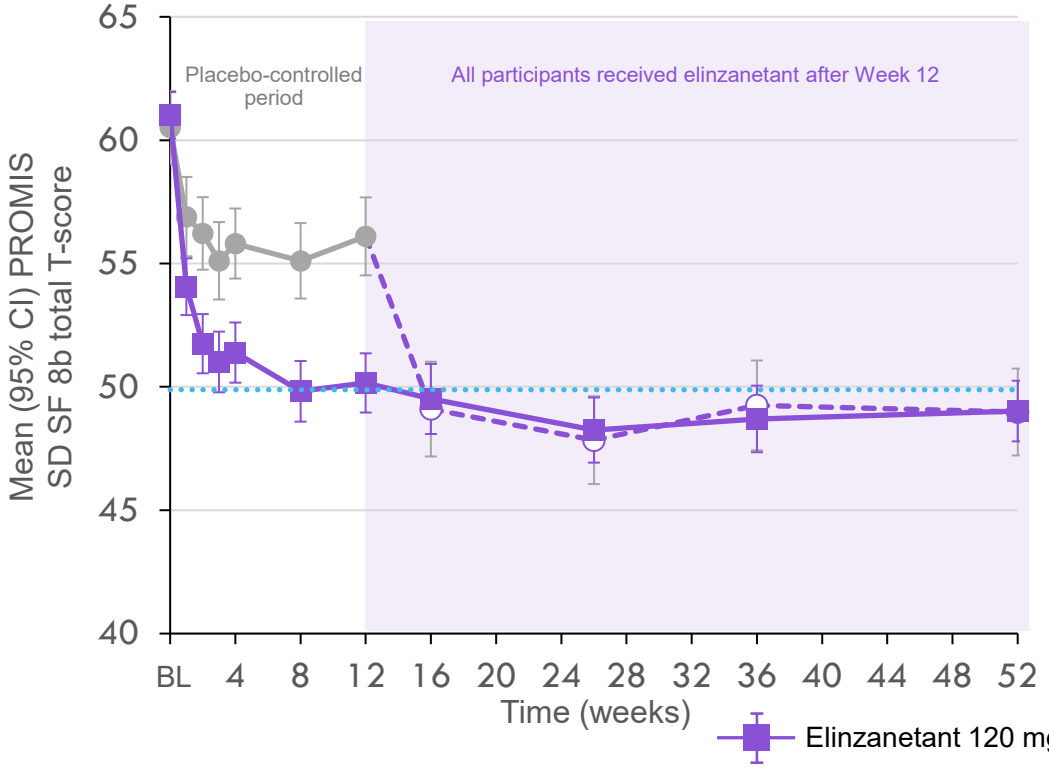
Participant demographics (FAS)

Characteristic	Tamoxifen (n=265)	Aromatase inhibitors (n=209)	GnRH (n=136)	No GnRH (n=338)
Age (years), mean (SD)	50.4 (6.8)	51.9 (7.7)	45.2 (5.7)	53.4 (6.4)
Duration of endocrine therapy (years), mean (SD)	2.1 (1.6)	1.8 (1.3)	1.7 (1.3)	2.0 (1.5)
Race, n (%)				
White	231 (87.2%)	187 (89.5%)	129 (94.9%)	289 (85.5%)
Black/African American	4 (1.5%)	3 (1.4%)	1 (0.7%)	6 (1.8%)
Hispanic/Latino, n (%)	6 (2.3%)	6 (2.9%)	2 (1.5%)	10 (3.0%)
Weight (kg), mean (SD)	71.0 (12.8)	72.9 (13.1)	69.5 (12.4)	72.8 (13.1)
BMI (kg/m^2), mean (SD)	25.9 (4.3)	26.9 (4.9)	25.4 (4.7)	26.7 (4.5)
Smoking history, n (%)				
Never	174 (65.7%)	135 (64.6%)	90 (66.2%)	219 (64.8%)
Former	58 (21.9%)	46 (22.0%)	25 (18.4%)	79 (23.4%)
Current	33 (12.5%)	28 (13.4%)	21 (15.4%)	40 (11.8%)

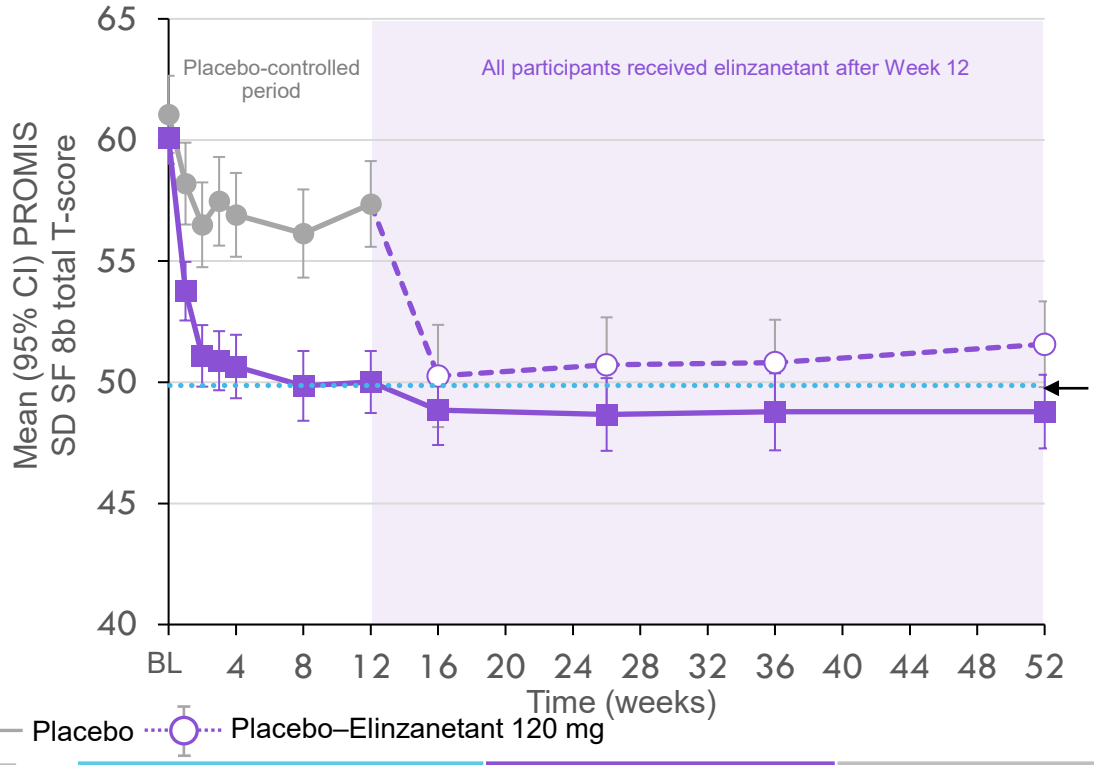
BMI, body mass index; FAS, full analysis set; GnRH, gonadotropin-releasing hormone; SD, standard deviation.

PROMIS SD SF 8b total T-score over time

Tamoxifen



Aromatase inhibitors



Level of sleep disturbance as measured by PROMIS SD SF 8b T-score scale:

- **Moderate** (60–70)
- **Mild** (55–60)
- **Normal** (<55)
- **US average‡** (50)

Elinzanetant 120 mg — Placebo — Placebo–Elinzanetant 120 mg

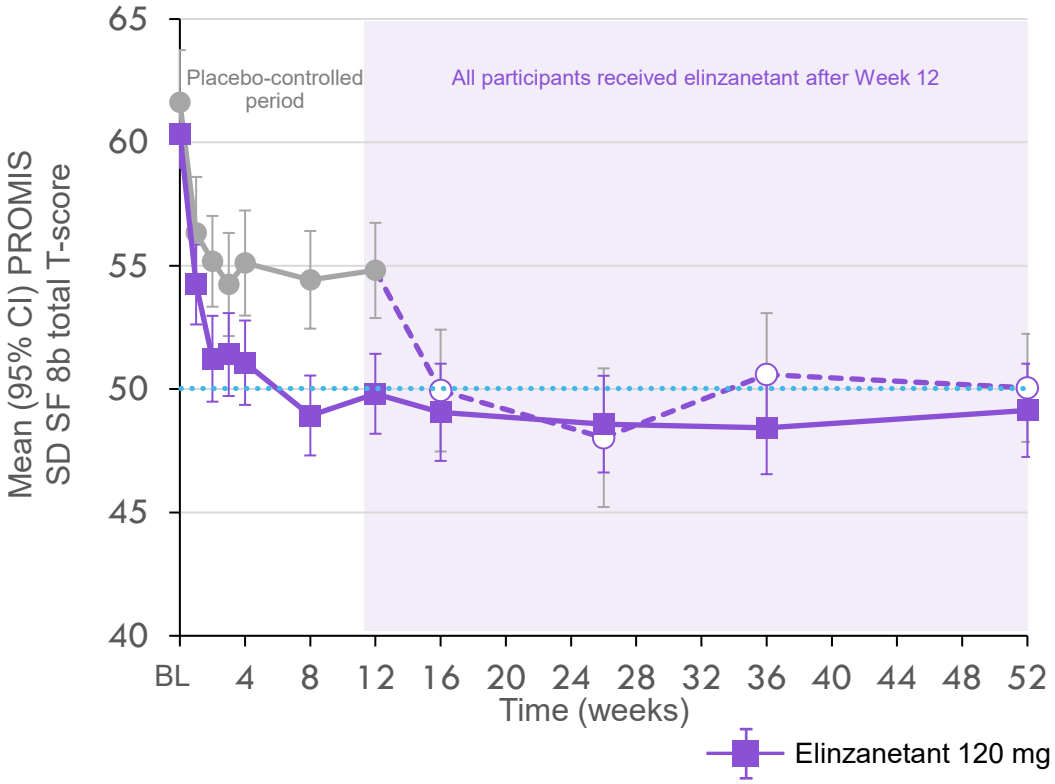
	Elinzanetant 120 mg (n=175)	Placebo (n=90)
Baseline, mean (95% CI)	61.0 (60.1, 61.9)	60.5 (59.0, 62.0)
Mean (95% CI) change from baseline to week 12	-11.0 (-12.3, -9.7)	-4,3 (-5.9, -2.6)

	Elinzanetant 120 mg (n=141)	Placebo (n=68)
Baseline, mean (95% CI)	60.1 (59.0, 61.2)	61.1 (59.5, 62.7)
Mean (95% CI) change from baseline to week 12	-10.0 (-11.4, -8.7)	-3.8 (-5.5, -2.0)

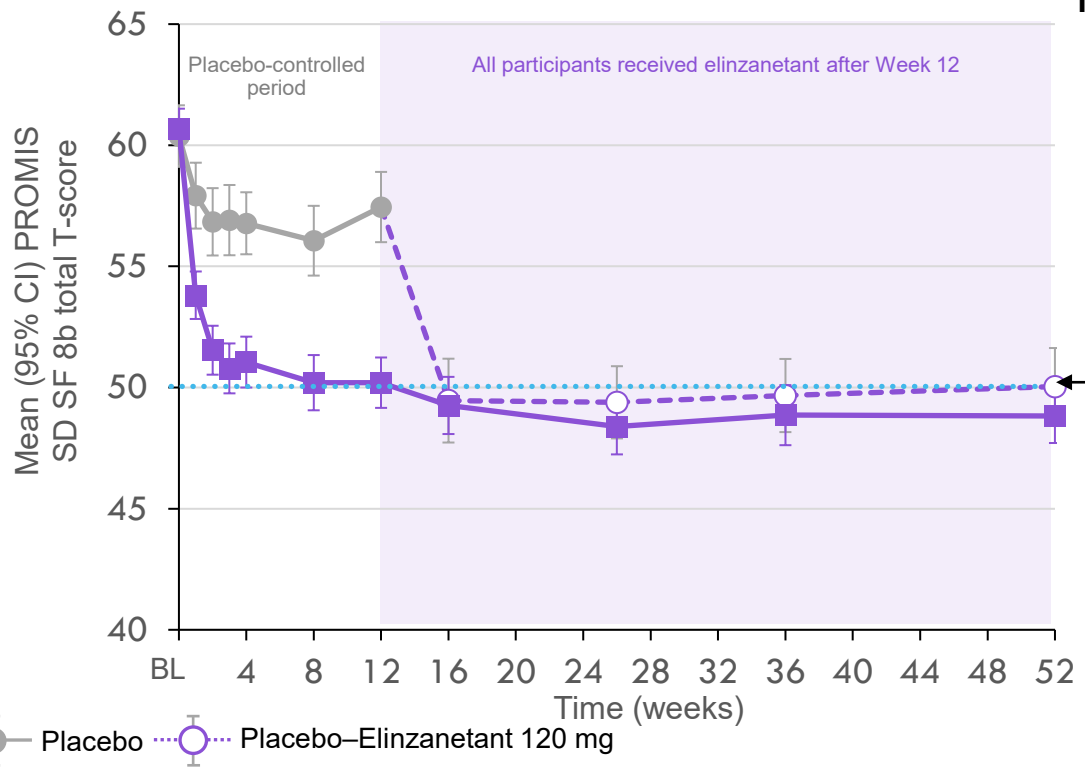
‡In a mixed clinical sample.
BL, baseline; CI, confidence interval; PROMIS SD SF 8b, Patient-Reported Outcomes Measurement Information System Sleep Disturbance Short Form 8b; US, United States.

PROMIS SD SF 8b total T-score over time

GnRH



No GnRH



Level of sleep disturbance as measured by PROMIS SD SF 8b T-score scale:

- **Moderate** (60–70)
- **Mild** (55–60)
- **Normal** (<55)
- **US average‡** (50)

Elinzanetant 120 mg — Placebo — Placebo–Elinzanetant 120 mg

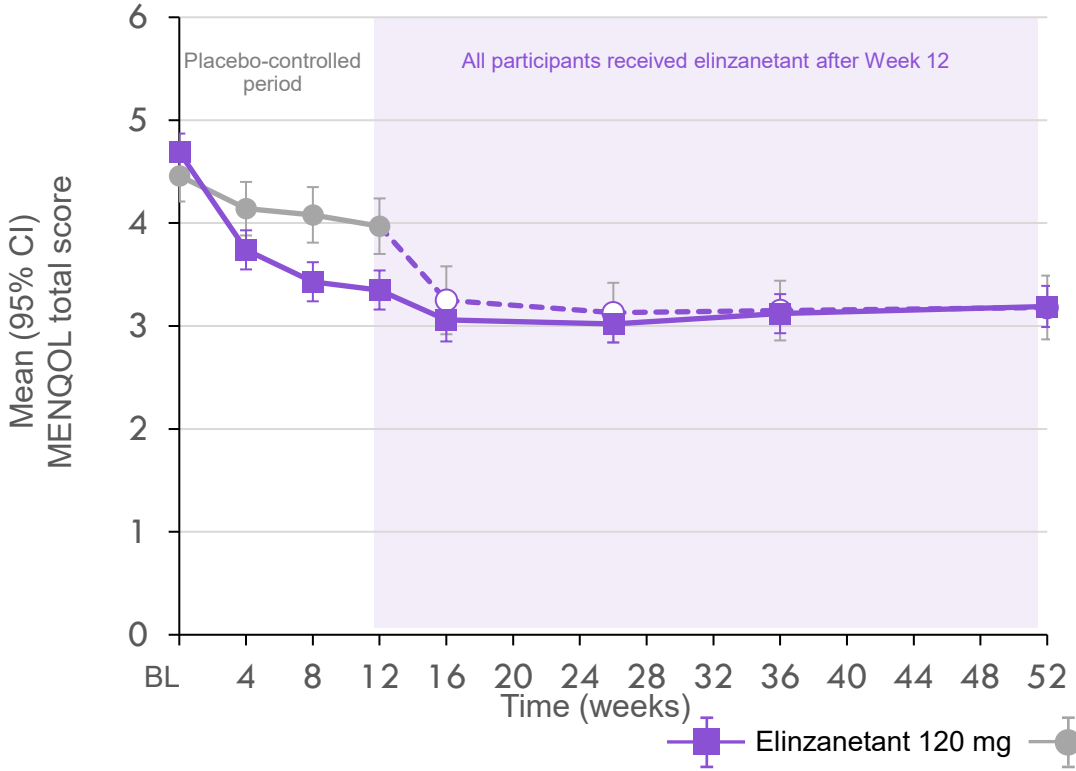
	Elinzanetant 120 mg (n=88)	Placebo (n=48)
Baseline, mean (95% CI)	60.4 (59.0, 61.7)	61.6 (59.5, 63.7)
Mean (95% CI) change from baseline to week 12	-10.4 (-12.1, -8.7)	-6.5 (-8.7, -4.2)

	Elinzanetant 120 mg (n=228)	Placebo (n=110)
Baseline, mean (95% CI)	60.7 (59.9, 61.5)	60.4 (59.1, 61.7)
Mean (95% CI) change from baseline to week 12	-10.6 (-11.8, -9.5)	-3.1 (-4.5, -1.7)

‡In a mixed clinical sample.
BL, baseline; CI, confidence interval; GnRH, gonadotropin-releasing hormone; PROMIS SD SF 8b, Patient-Reported Outcomes Measurement Information System Sleep Disturbance Short Form 8b; US, United States.

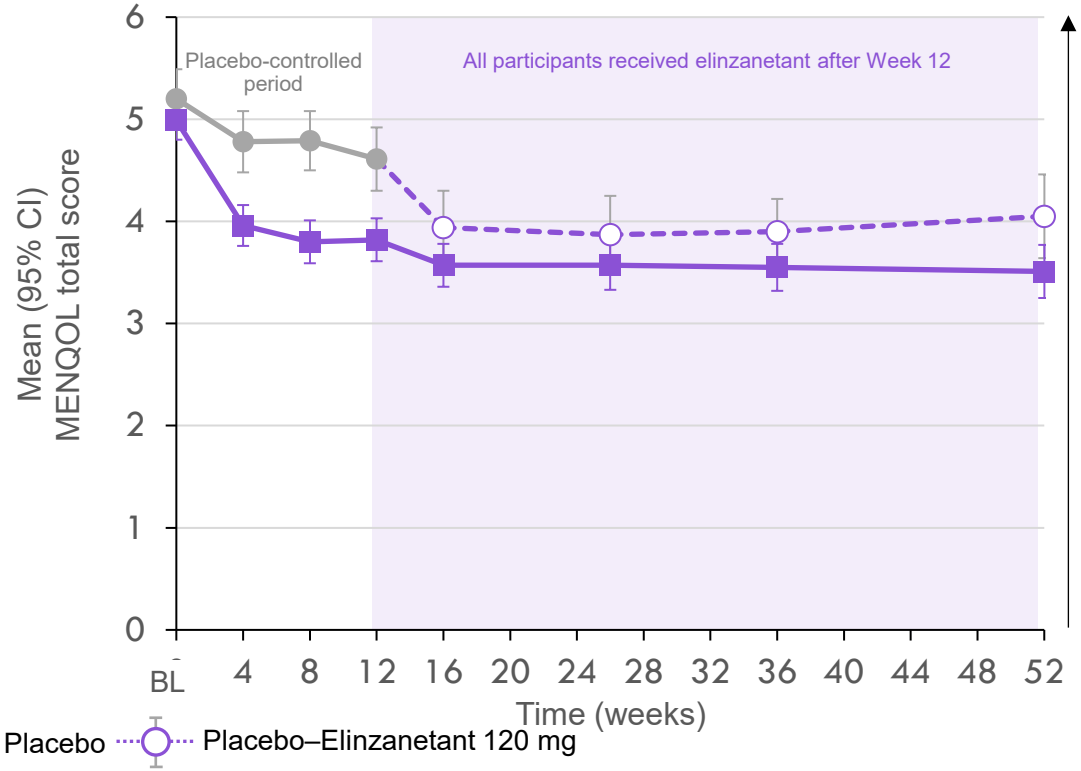
MENQOL total score over time

Tamoxifen



	Elinzanetant 120 mg (n=175)	Placebo (n=90)
Baseline, mean (95% CI)	4.7 (4.5, 4.9)	4.5 (4.2, 4.7)
Mean (95% CI) change from baseline to week 12	-1.4 (-1.6, -1.2)	-0.5 (-0.7, -0.3)

Aromatase inhibitors



	Elinzanetant 120 mg (n=141)	Placebo (n=68)
Baseline, mean (95% CI)	5.0 (4.8, 5.2)	5.2 (4.9, 5.5)
Mean (95% CI) change from baseline to week 12	-1.2 (-1.4, -1.0)	-0.6 (-1.0, -0.3)

Level of bother as measured by MENQOL total score:

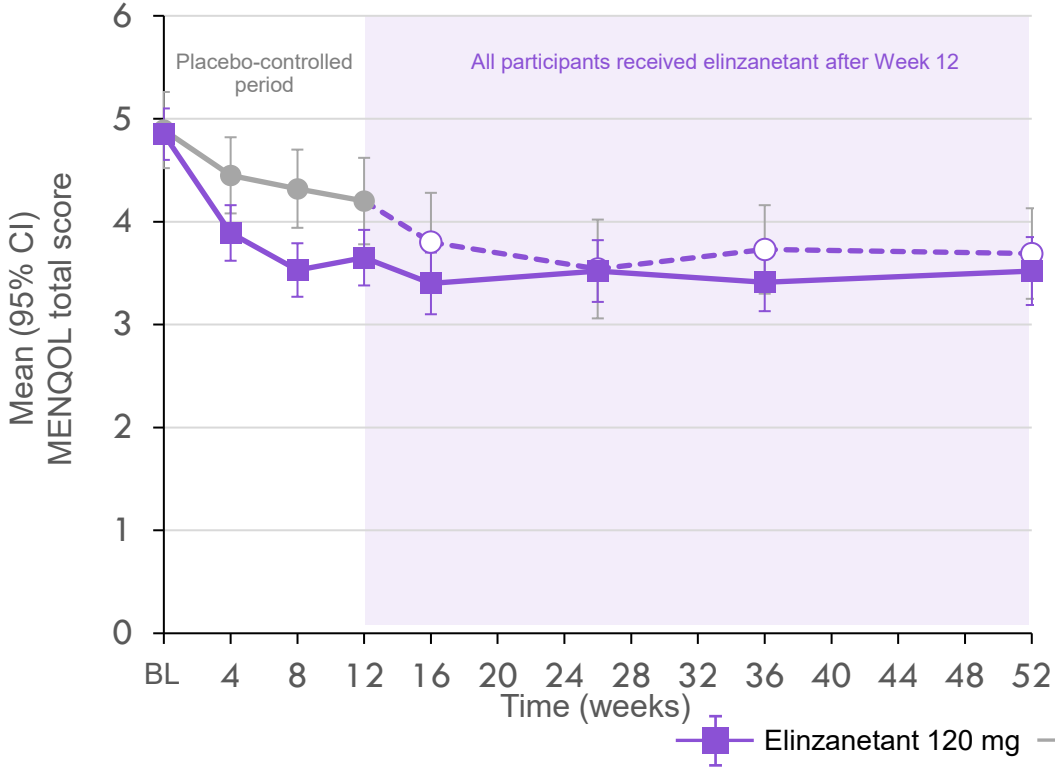
Increasing degree of bother, from **1** (not at all bothered) to **8** (extremely bothered)

Elinzanetant 120 mg — Placebo — Placebo–Elinzanetant 120 mg

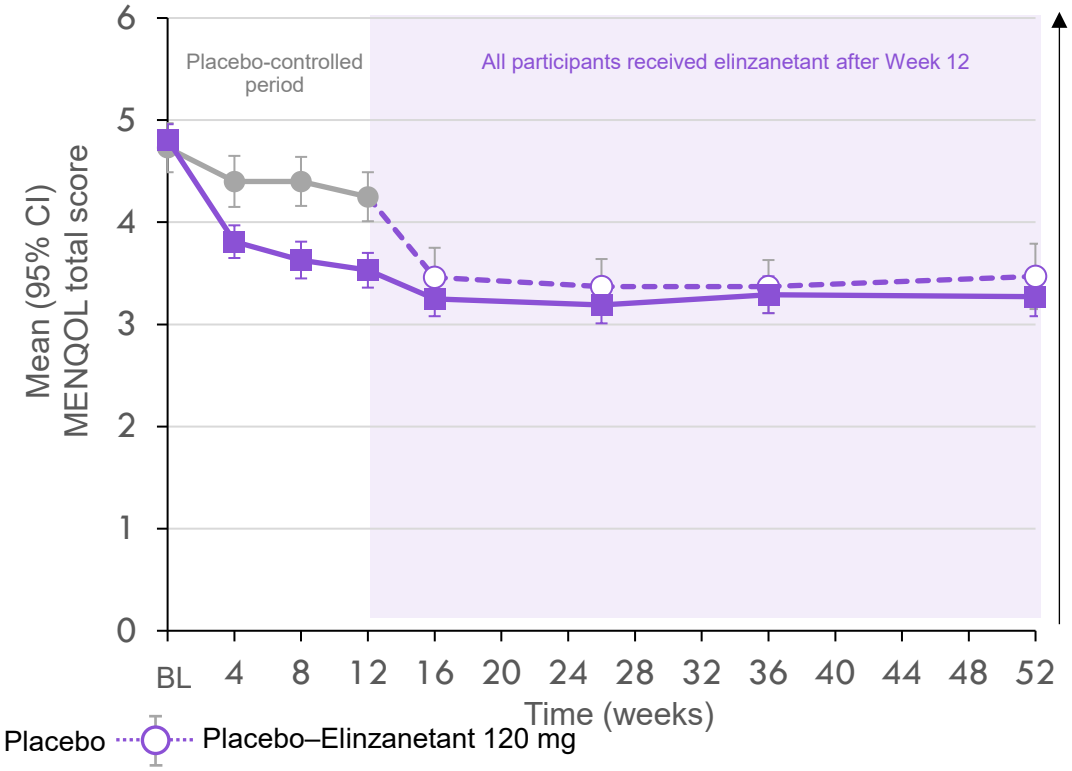
BL, baseline; CI, confidence interval; MENQOL, Menopause-specific Quality Of Life questionnaire.

MENQOL total score over time

GnRH



No GnRH



Level of bother as measured by MENQOL total score:

Increasing degree of bother, from **1** (not at all bothered) to **8** (extremely bothered)

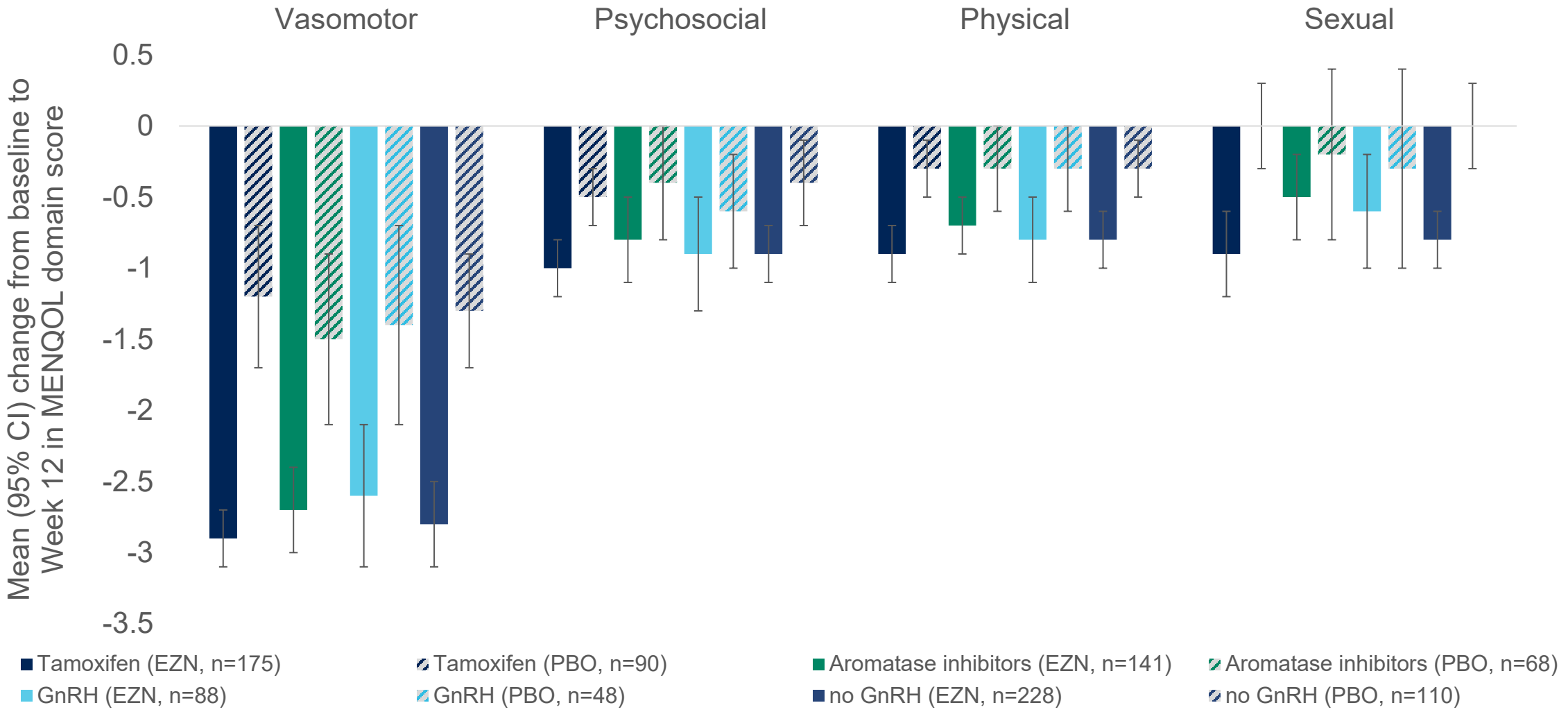
Elinzanetant 120 mg — Placebo — Placebo–Elinzanetant 120 mg

	Elinzanetant 120 mg (n=88)	Placebo (n=48)
Baseline, mean (95% CI)	4.9 (4.6, 5.1)	4.9 (4.5, 5.3)
Mean (95% CI) change from baseline to week 12	-1.2 (-1.5, -1.0)	-0.6 (-1.0, -0.3)

	Elinzanetant 120 mg (n=228)	Placebo (n=110)
Baseline, mean (95% CI)	4.8 (4.7, 5.0)	4.7 (4.5, 5.0)
Mean (95% CI) change from baseline to week 12	-1.3 (-1.5, -1.2)	-0.5 (-0.7, -0.3)

BL, baseline; CI, confidence interval; GnRH, gonadotropin-releasing hormone; MENQOL, Menopause-specific Quality Of Life questionnaire.

Change from baseline to week 12 in MENQOL domain scores



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CI, confidence interval; EZN, elinzanetant; GnRH, gonadotropin-releasing hormone; MENQOL, Menopause-specific Quality Of Life questionnaire; PBO, placebo.

Conclusions

Elinzanetant demonstrated rapid and sustained improvements in sleep disturbance and menopause-related quality of life compared with placebo irrespective of the type of endocrine therapy

Improvements were also seen in vasomotor, psychosocial, physical, and sexual aspects of menopause-related quality of life

Taken with previous data, findings support the efficacy of elinzanetant in reducing VMS frequency and severity, as well as sleep disturbance, and improving menopause-related quality of life independently of the type of endocrine therapy

To date, these are the only data demonstrating the efficacy of an NKT in women with breast cancer across different types of endocrine therapy

NKT, neurokinin-targeted therapy; VMS, vasomotor symptoms.

Acknowledgements

- The authors would like to thank the investigators and participants of the OASIS-4 trial